Thromboelastometry-based Assessment of Coagulation In Aortic Dissection

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26674

Source
NTR

Brief title
TACIT

Health condition

Aortic dissection, both elective and emergency aortic surgery

Sponsors and support

Primary sponsor: Department of Anesthesia, Amsterdam UMC, location AMC
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Comparison of standard-of-care thromboelastometry with ROTEM® Delta and ROTEM® Sigma at different timepoints perioperatively, in patients undergoing elective and emergency aortic surgery

Secondary outcome

Incidence and degree of perioperative coagulation abnormalities, transfusion and coagulation factor requirements, complications, mortality, and morbidity up to 30 days postoperatively, in patients undergoing elective and emergency aortic surgery

Study description

Background summary

The aim of the present retrospective and prospective data collection is to estimate the incidence and degree of perioperative coagulation abnormalities using thromboelastometry (with both ROTEM® Delta and ROTEM® Sigma) as well as transfusion and coagulation factor requirements in patients undergoing aortic surgery (emergency and elective). We will collect data on patients scheduled for emergency surgery, due to acute type A aortic dissection and patients undergoing elective surgery of the aorta. Furthermore, we will compare the results from viscoelastic testing using ROTEM® Delta with ROTEM® Sigma.
The findings may help to optimize coagulation management in patients undergoing major aortic surgery, in order to minimize bleeding as well as thromboembolic complications, both of which can have devastating consequences in this high-risk patient population.

Study objective

The aim of the present retrospective and prospective data collection is to estimate the incidence and degree of perioperative coagulation abnormalities, using thromboelastometry (with both ROTEM® Delta and ROTEM® Sigma), as well as transfusion and coagulation factor requirements, in patients undergoing elective and emergency aortic surgery.

Study design

All available perioperative timepoints: T0 = Baseline (before aortic cross-clamp), T1 = after aortic cross-clamp, T2 = admission to ICU, T3 = post-op day 1 ICU, T4,5= (optional) daily on ICU until discharge from ICU, T6 = 30 day follow-up for morbidity and mortality

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

• Patients > 18 years
• Patients already operated on or scheduled for acute or elective aortic surgery in Amsterdam UMC, location AMC in period 01 January 2021 - 31 December 2021
• Willing and able to sign consent letter for the re-use of care data

Exclusion criteria

• Previous history of manifest coagulation disorders

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-06-2021
Enrollment:	200

Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	06-06-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9530
Other	METC AMC : W21_186#21.201

Study results